Serial No.: 10/804,331

Filed: March 19, 2004

Page 2 of 7

A. At least one specific non-structural protein as stated in claim 2 or non-structural proteins 1-4 as stated in claim 3.

- B. At least one specific IRES as stated in claim 4.
- C. A specific heterologous nucleic acid as stated in claims 6-9.
- D. One specific virus from each of claims 11-14.
- E. A specific percentage of control as stated in claims 15 and 16.
- F. A specific nucleic acid as stated in claims 17 and 18.
- G. A specific length as stated in claims 20-22.
- H. A specific helper nucleic acid as stated in claims 38, 39, 43 and 44.

Applicants provisionally elect Group I (claims 1-36, 47-51 and 57-59) and also provisionally elect the following species, all with traverse:

A. Applicants respectfully point out that claim 2 recites a "contiguous nucleotide sequence encoding alphavirus nonstructural proteins nsp1, nsp2, nsp3 and nsp4. Thus, the claim as written does not provide for an embodiment wherein the second nucleic acid of claim 2 is only nsp1, nsp2, nsp3 or nsp4. Thus, it is not possible for applicants to elect an embodiment reciting only one specific non-structural protein of claim 2, because nsp1, nsp2, nsp3 and nsp4 as recited in claim 2 are not separate species and such an election would be a departure from the spirit and intent of applicants' invention. Thus, applicants provisionally elect the contiguous nucleotide sequence encoding nsp1, nsp2, nsp3 and nsp4 as recited in claim 2 for the purposes of examination, with traverse. Applicants also remind the Examiner that upon allowance of an elected species, applicants will be entitled to consideration of additional species recited in the

Serial No.: 10/804,331

Filed: March 19, 2004

Page 3 of 7

claims that are written in dependent form or otherwise include the limitations of an allowed claim.

- B. Applicants provisionally elect mammalian virus IRESs of claim 4, again with the reminder to the Examiner that upon allowance of an elected species, applicants are entitled to consideration of additional species recited in the claims.
- C. Applicants provisionally elect the species wherein the heterologous nucleic acid is a protein, as recited in claim 6, again with the reminder to the Examiner that upon allowance of an elected species, applicants are entitled to consideration of additional species recited in the claims.
- D. Applicants provisionally elect VEE as the virus of claims 10-14, again with the reminder to the Examiner that upon allowance of an elected species, applicants are entitled to consideration of additional species recited in the claims.
- E. Applicants provisionally elect the percentage of control of 10%, as recited in claims 16, again with the reminder to the Examiner that upon allowance of an elected species, applicants are entitled to consideration of additional species recited in the claims.
- F. Applicants provisionally elect the nucleic acid RNA, as recited in claim 17, again with the reminder to the Examiner that upon allowance of an elected species, applicants are entitled to consideration of additional species recited in the claims.
- G. Applicants provisionally elect the specific length of 25-7500 nucleotides, as recited in claim 21, again with the reminder to the Examiner that upon allowance of an elected species, applicants are entitled to consideration of additional species recited in the claims.

Serial No.: 10/804,331

Filed: March 19, 2004

Page 4 of 7

H. Applicants provisionally elect the helper nucleic acid of claim 3, again with the reminder to the Examiner that upon allowance of an elected species, applicants are entitled to consideration of additional species recited in the claims.

Applicants' traversal of this restriction is on the basis that the Examiner has not demonstrated that the requirements for claim restriction have been met. In particular, it is stated in section 803 of the MPEP that two criteria for proper restriction of claims must be met: 1) The inventions must be independent and distinct as claimed, AND 2) there must be a serious burden on the examiner if restriction is required. The MPEP further states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

In particular, the examiner has not met the second criterion because there is no evidence provided that it would be a serious burden to examine the claims and species together. The MPEP states that "[f]or purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP 808.02." Applicants believe that the Examiner has not met the requirements of a *prima facie* showing of why a search of all of the species of the claims of Group I together would pose a serious burden. Thus, applicants respectfully request that this restriction, particularly as it regards species, be reconsidered and withdrawn in order to facilitate efficient prosecution of this application.

Specifically, with regard to the traversal of the requirement to elect the various species recited in the Action, applicants provide the following remarks.

Serial No.: 10/804,331 Filed: March 19, 2004

Page 5 of 7

With regard to an election of species of an IRES in claim 4 and an election of species of alphavirus in claims 10-14, all of which are presented in a Markush grouping format, applicants respectfully point out that MPEP § 803.02 states in relevant part as follows.

A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). The members of the Markush group (A, B, and C in the example above) ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property. Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology are most frequently claimed under the Markush formula but purely mechanical features or process steps may also be claimed by using the Markush style of claiming. See MPEP § 2173.05(h).

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions.

In view of the above language, applicants respectfully point out that in the elected claim set, claim 4 recites a Markush group of representative species of the genus of IRESs. There are a total of five species described, thus demonstrating that they are few in number and they are all closely related on the basis that they are all members of the same genus of IRES that are defined and identified by those of skill in the art by having "one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property." One of skill in the art would know that all IRESs by definition have the same function of allowing cap-independent translation to be initiated internally on a transcript and all IRES are recognized by those of skill in the art as

Serial No.: 10/804,331

Filed: March 19, 2004

Page 6 of 7

having specific structural features in common to facilitate this common function. Thus, the criteria for examining all of the IRES species of claim 4 together as a Markush group are met and it is appropriate that all five of these IRESs be searched and examined together and applicants respectfully request that the Examiner proceed accordingly.

Furthermore, with regard to the alphaviruses recited in claims 10-14, again applicants point out that claims 10-14 recite a Markush group of representative species of the genus of alphaviruses. There are a total of seven species described, thus demonstrating that they are few in number and they are all closely related on the basis that they are all members of the same genus of alphaviruses that are defined and identified by those of skill in the art by having "one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property."

One of skill in the art would know that all species of the genus of alphaviruses by definition have a similar genomic organization and replication function and all alphaviruses are recognized by those of skill in the art as having specific structural features in common to facilitate this common function. Thus, the criteria for examining all of the alphavirus species of claims 10-14 together as a Markush group are met and it is appropriate that all seven of these alphaviruses be searched and examined together and applicants respectfully request that the Examiner proceed accordingly.

Also, the requirement for election of 1) either RNA or DNA, as set forth in claims 17 and 18; 2) either 80% or 10%, as set forth in claims 15 and 16; and 3) either 30 nucleotides, between 25 and 7500 nucleotides and between 150 and 1000 nucleotides, as set forth in claims 20-22, respectively, is traversed herein on the basis that these species restrictions are unduly narrowing and prejudicial to applicants and the Examiner has provided no reasonable basis for why these embodiments could not be searched and examined together without undue burden, particularly

Serial No.: 10/804,331

Filed: March 19, 2004

Page 7 of 7

where the searches of the various respective embodiments would be expected to be co-extensive.

Thus, applicants respectfully request reconsideration and withdrawal of these species election

requirements, such that the search and examination of all of these embodiments of this invention

can be carried out in the present application in the interest of efficient and compact prosecution

of this application pursuant to USPTO Patent Business Goals (65 Fed. Reg. 54603, September 8,

2000).

Furthermore, if the claims of Group I are found to be allowable, applicants request that

the Examiner review the claims of the other groups according to the practice of rejoinder as set

forth in section 821.04 of the MPEP. In particular, it is stated therein that if a product claim is

elected in a restriction and then found allowable, withdrawn process claims that depend from or

otherwise include all the limitations of the allowable product claim are to be rejoined.

The Examiner is encouraged to contact the undersigned directly if such contact will

expedite the search and examination of the pending claims and their allowance to issue.

No fee is believed due with this response. However, the Commissioner is authorized to

charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

USPTO Customer No. 20792

Myers Bigel Sibley & Sajovec, P.A.

P. O. Box 37428

Raleigh, North Carolina 27627

Telephone: (919) 854-1400

Facsimile: (919) 854-1401

Respectfully submitted,

Mary L. Miller

Registration No. 39,303

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the

U.S. Patent and Trademark Office on July 2, 2007.

Typed or Printed Name of Person Signing Certificate: Evelyn Casey